JUN 2 4 2002

Nicolet
BIOMEDICAL

K021144

Summary of Safety and Effectiveness

Company Name:	Nicolet Biomedical 5225 Verona Road Madison, WI 53711
Contact:	Glen Hermanson, Manager of Standards and Compliance
Phone:	608 441-2065
Fax:	608 441-2007
Summary Date:	April 3, 2002
Trade Name:	Subdural Strip Electrodes
Common Name:	Cortical Electrode
Classification Name:	21 CFR 882.1310; Product Code: GYC

Predicate Device:

510(k) Number:	K970587, K923803, K850342
Manufacture:	Ad-Tech Medical Instrument Corp.
Trade Name:	Subdural Electrode

1.0 Description of Device

Subdural Strip Electrodes are used by licensed medical professionals to support stimulation and recording of biopotentials from the surface of the brain or the subdural space above the surface of the brain. The electrodes connect to medical equipment in support of stimulation and recording.

The electrodes are provided to the user sterile. The electrodes are single patient use, disposable devices.

2.0 Intended Use

The intended use of the Nicolet Subdural Strip Electrodes is the same as the predicate electrodes. The Nicolet Subdural Strip Electrodes can be temporally placed on the surface of the brain or subdural space in support of stimulating the brain or recording the brain's electrical activity.

3.0 Technological

The Subdural Strip Electrodes are made from the same materials as the predicate devices. The electrode lead wires terminate in a safety connector, complying with the FDA Performance Standard for Lead Wires and Patient Cables, 21 CFR Part 898.

These electrodes do not contain active electronics or software. The electrodes connect to the user's medical equipment.

4.0 Conclusions

The intended use and technology of the Nicolet Subdural Strip Electrodes is substantially equivalent to the predicate electrodes. No new questions of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Nicolet Biomedical, Inc.
c/o Mr. Gary Syring
Quality & Regulatory Associates, LLC
800 Levanger Lane
Stoughton, Wisconsin 53589

Re: K021144
Trade/Device Name: Nicolet Biomedical/Subdural Strip Electrode
Regulation Number: 882.1310
Regulation Name: Cortical Electrode
Regulatory Class: II
Product Code: GYC
Dated: April 5, 2002
Received: April 9, 2002

Dear Mr. Syring:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K021144

Device Name: Nicolet Subdural Strip Electrodes

Indications For Use:

The Nicolet Subdural Strip Electrodes can be temporarily placed on the surface of the brain or subdural space in support of stimulating the brain or recording the brain's electrical activity.

(PLEASE: DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021144

(Optional Format 3-10-98)